Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Claims 1, 3-5, 7-11, and 14-17 have been amended. Claims 1-17 remain pending in the application. Claims 1, 14, and 15 are independent. The sole rejection is respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

Claims 1, 3-5, 7-11, and 14-17 have been amended in response to the examiner's remarks at Office Action page 4 regarding "an intended use of an article." As amended, each of claims 1, 3-5, 7-11, and 14-17, as well as previously presented claims 2, 6, and 12, defines a device that is structurally different from each of the applied prior art devices. Entry of each of the amendments is respectfully requested.

35 U.S.C. § 103(a) - Goux and Storey

Claims 1-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,567,320 to Goux et al. (hereinafter "Goux") in view of US 4,202,760 to Storey et al. ("Storey").

The rejection of claims 1-17 under § 103(a) over Goux and Storey is respectfully traversed. The combined disclosures of Goux and Storey would not have rendered obvious Applicants' claimed invention.

As explained in Applicants' response to the first Office Action filed January 11, 2007, Applicants' invention is based on the following (see instant specification page 10, line 18, through page 11, line 3). Conventional hemodialyzers can determine the blood purification performance of the blood purification element (i.e., the dialysance of the dialyzer) in relation to a first material. For example, the sodium ion dialysance can be determined based on the change in its concentration relative to that in the fresh dialysis fluid.

However, it may also be necessary or desirable to determine the performance of the blood purification element in relation to a second material. See, e.g., Applicants' disclosure regarding the concentrations of potassium, calcium, and phosphate (specification page 23, line 33, through page 24, line 10).

Thus, an object of Applicants' device is "to determine the second blood purification performance, which is different from the first blood purification performance, for a second material, without a further measurement method being necessary" (specification page 10, lines 18-22). Applicants' device is based on "relationships between the two blood purification performances which are stored in an analysis unit and which go beyond a mere identity assignment for identical blood purification performances as in the case of sodium ions and urea, [so that] the second blood

purification performance may be determined directly" (specification page 10, lines 23-29).

Therefore, Applicants' instant claim 1 defines a device that includes in pertinent part:

> at least one sensor on at least one of the blood loop or the dialysis fluid loop, the sensor being configured to detect and measure a concentration of a first material capable of penetrating the semipermeable membrane, and
>
> an analysis unit operatively connected to the at least one sensor and configured to determine i) a blood purification performance L1 of the blood purification element for the first material based on the measurement values of the at least one sensor and *ii) a blood purification performance L2 of the blood purification element for a second material, which is different from the blood purification performance L1 for the first material, based on the blood purification performance L1 for the first material.*

The combined disclosures of Goux and Storey do not teach all of Applicants' claim features. Neither Goux nor Storey teaches an analysis unit that is configured to determine the blood purification performance L1 of the blood purification element according to Applicants' claimed invention.

The examiner asserts that Goux's "analysis unit 22 is capable of determining the blood purification performance (col. 5, lines 14-59)" (Office Action page 3). The examiner then acknowledges, however, that "Goux does not disclose the device differentiates between two materials . . ." (Office Action page 3).

The examiner is correct in concluding that "Goux does not disclose the device differentiates between two materials . . ." In

fact, in the disclosure relied upon by the examiner (specifically, col. 5, lines 24-31), Goux teaches that

> It is by virtue of this correlation that it is possible to calculate the real concentration (Cbin) of blood sodium at the inlet of the exchanger from four measured values of the conductivity of the dialysis fluid (Cd1in, Cd2in, Cd1out, Cd2out, respectively the conductivity at the inlet and the outlet of the exchanger, *measured during the successive passage of a first and of a second dialysis fluid d1, d2 having different conductivities*) . . . (Emphasis added)

Thus, Goux calculates a concentration of blood sodium by measuring conductivity during the successive passage of a first and a second dialysis fluid d1, d2 having different conductivities. But, Goux's device is different from Applicants' claimed invention in that Goux is not configured to differentiate between two materials. As indicated above, an object of Applicants' claimed invention is "to determine the second blood purification performance, which is different from the first blood purification performance, for a second material, without a further measurement method being necessary."

Storey's apparatus is also structurally different from Applicants' claimed device. Storey is directed to an "Apparatus and Method for Preparation of a Hemodialysis Solution Optionally Containing Bicarbonate." The examiner relies upon Storey's disclosure at column 5, lines 1-62. But there, Storey summarizes his invention as follows: "The method of this invention, and the apparatus in loops 50 and 40, provide a spectrum of bicarbonate-

acetate containing hemodialysis solutions ranging from no bicarbonate to no acetate" (column 5, lines 34-37). The examiner also relies upon Storey's disclosure at column 1, lines 45-50. There, Storey discloses that "[t]his invention provides a hemodialysis system which enables continuous formulation and supply to an artificial kidney of a hemodialysis solution, or dialysate, which contains the normally present sodium acetate component, or optionally may contain bicarbonate as a partial or total replacement therefor." Story, therefore, is directed to a sensor *for freshly prepared dialysate*, and fails to disclose Applicants' claimed device that includes, *inter alia*, an analysis unit that is configured *to determine the blood purification performance*.

And, regardless of what Storey may disclose with regard to the composition of the dialysate (column 5, lines 1-62), the disclosure of Storey does not rectify any of the above-described deficiencies of Goux. Thus, the combined disclosures of Goux and Storey do not teach all of Applicants' claim features.

Furthermore, there is no teaching in either Goux or Storey that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' pending claims. As indicated above, Goux is directed to a device that is able "to calculate the real concentration (Cbin) of blood sodium at the inlet of the exchanger from four measured values of the conductivity of the dialysis fluid."

Storey is directed to *preparation* of a hemodialysis solution optionally containing bicarbonate. There is simply no teaching in either Goux or Storey that would have led one to select the references and combine them, let alone in a way that would produce Applicants' claimed invention. Applicants' claimed device is configured not only to determine the blood purification performance, but to do so by determining "i) *a blood purification performance L1 of the blood purification element for the first material based on the measurement values of the at least one sensor* and *ii) a blood purification performance L2 of the blood purification element for a second material,* which is different from the blood purification performance L1 for the first material, *based on the blood purification performance L1 for the first material.*"

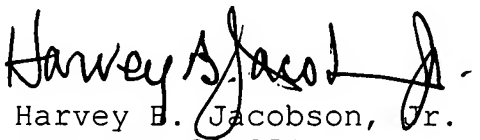
Finally, the examiner concludes that "[i]t would have been obvious . . . to provide the invention of Goux with the ability to monitor the blood purification of claimed materials for the benefit of returning to the patient blood with a normal concentration of the materials, which Storey teaches is desired (Storey col. 1, lines 45-50). But, as indicated above, Storey simply discloses at col. 1, lines 45-50, that "[t]his invention provides a hemodialysis system which enables continuous formulation and supply to an artificial kidney of a hemodialysis solution, or dialysate, which contains the normally present sodium acetate component, or optionally may contain bicarbonate as a partial or

total replacement therefor." Therefore, contrary to the assertion in the Office Action, Storey does not disclose the asserted "ability to monitor the blood purification of claimed materials." There is, therefore, simply no teaching in either Goux or Storey that would have led one to select the references and combine them, let alone in a way that would produce Applicants' claimed invention.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 
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